THE EFFECT OF NECK STABILIZATION EXERCISE PLUS CARDIOPULMONARY REHABILITATION ON PULMONARY FUNCTION OF SCI

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1. Introduction

Spinal cord injury(SCI) is a central nervous system disease caused by various accidents such as falling injury. It might lead to not only extremities disability but also respiratory damage[1-3]. Respiratory dysfunction might result in elevated risk of pulmonary complication such as pneumonia, secretion retention, atelectasis and so on[4, 5], and it might further result to other morbidity, mortality, and economic burden[6]. The impairment of respiratory function is determined by the level of injury, completeness of injury, and onset time from injury[7]. Acute SCI is defined as onset within 12~18 months[8]. The respiratory problems are prone to present during this era. According to previous textbook, patients at injury level C3~C5 might remain 30% predicted total lung capacity (TLC)[9]. It can be attributed to paralysis of the other muscles of inspiration (inspiratory intercostals and scalenes)[9-11]. Patients at injury level C7~T4 might preserve 30~50% predicted TLC and patient at injury level T5～T10 might retain 75%~100% predicted TLC. It could be speculated that the major muscles of expiration (abdominals and expiratory intercostals) and inspiratory intercostals damage[9-11]. The residual volume (RV) relatively increased because of undermined expiratory musculature and subsequent reduced expiratory reserve volume[12]. Forced expiratory volume in one second (FEV1) also decline owing to expiratory muscle and inspiratory muscle dysfunction and respiratory tract resistance increasing[13]. Recent article also reported plasma CRP and IL-6 in individuals with chronic SCI are inversely associated with $FEV_{1.}$ It certainly refered that worse pulmonary function was asscociated with higher inflanmantion situation[14]. Furthermore, some patients even show dyspnea during their daily activity[15]. Some articles mention the imbalance between capacity and demand of respiratory function, enhance the risk of respiratory muscle fatigue, dyspnea, and exercise intolerance[16, 17]. Hence, the treatment goals of SCI patients' respiratory function are training their remained parts as complete as possible and preventing further respiratory complication, dyspnea as well[9].

Pulmonary rehabilitation composed of respiratory muscle training and cough ability training has been proved necessary and effective for SCI patients[9]. Based on previous articles, respiratory muscle training including diaphragm and intercostal muscle can enhance respiratory muscle strength and endurance, pulmonary function such as vital capacity(VC), TLC, $FEV_{1,}$ and can ameliorate respiratory complication[9, 18, 19]. Furthermore, cough ability is also important because it can assist patient sweap out the sputum and can maintain air tract hygiene[9, 20, 21]. According to Reid et al., Studies examining insufflation combined with manual assisted cough provided the most consistent, high-level evidence of secretion removal.

Besides pulmonary rehabilitation, respiratory accessory muscle course is also essential for some SCI patiets who are either in acute stage or high level lesion (above C3)[22]. Accessory muscles such as scalenes, SCM, pectoralis muscle, and Trapezius are able to compensate lost diaphragm and intercostal muscle's function[9, 23, 24]. Nevertheless, accessory muscles tend to be fatigue. Moreover, overusing of neck accessory muscle might bring about neck pain and discomfort[25, 26]. Therefore, augumentation of the endurance and strength of these muscle can be regard as treatment goal for acute SCI patients.

Cervicocranial flexion exercise (CCFE) and superficial neck flexor endurance training have been widely implemented in clinical practice for curing chronic neck pain[27]. By means of CCFE, the muscle balance between deep neck flexor and superficial flexor would be optimal during neck movement. In other words, the superficial neck flexor(scalenes, SCM, and trapezius) would not overactive and the fatigue threshold might

increase[28-30]. Superficial neck flexor endurance training is proved to be efficient in reducing superficial cervical flexor muscle fatigue as well as increasing cervical flexion strength[25].

Reasonably, Cervicocranial flexion exercise (CCFE) and superficial neck flexor endurance training are also beneficial to pulmonary function due to training the respiratory accessory muscle (scalens and SCM). Hence this article hypothesizes that Cervicocranial flexion exercise (CCFE) and superficial neck flexor endurance training combined with common pulmonary rehabilitation will manifest better outcomes (pulmonary function, dyspnea situation, pain and stifness level of neck) than pulmonary rehabilitation only.

2. Method

2.1 subject

Patients were recruited in this article during 2020/03 to 2021/02. The inclusion criteria were 1.) SCI onset in a year; 2.) motor level above T12 and American Spinal Injury Association Impairment Scale (AIS) grade A, B, C, or D; 3.) age from 20~70; 4.) FEV_1< 80% prediction value. The exclusion criteria were 1.) ventilation depedence 2.) Tracheostomy 3.) Psychiatric condition 4.) Progressive diseases 5.) infection 6.) cancer 7.)unable to speak Chinese or English. Patient who met the criteria would were asked to provide written informed consent. The IRB were approved by Tao Yuan General Hoapital, Ministery of Health and Welfare, IRB committee.( )

2.2 procedure

The subjects included in this study were randomized assigned to experimental group and control group. The randomization orders were decided by computer, and all the contents were concealed into a dark color envelop. Before first treatment, the envelops were opened to determine which treatment protocal were adopted. The treatmet of experimental group was consist of Cervicocranial flexion exercise (CCFE) and neck flexor endurance training plus normal cardiopulmonary rehabilitation. The treatmet of control group was composed of general neck stretch exercise plus cardiopulmonary rehabilitation. Subsequently, initial measurement was conducted including lung capacity test, dyspnea situation, pain and stiffness of neck. Moreover, lung function such as FVC and FEV_1, dyspnea situation, pain and stiffness of neck were also recorded one time in a week as a short-term outcome. Then, the treatment protocals were both executed for 30 minutes, ten times in a month. After completing the treatment process, the final measurement were conducted as the initial treatment. All the outcome were collected and analyzed by statistically method.

2.3 Outcome measurement

Lung capacity was evaluated by in lung function examination center of Taoyaun general hospital. The parameters () revealed by this test. Before the examination, bronchodilator shold not be used to avoid interfering the outcome of examination. In addition, portable lung cacity device(ezOxygen, Taipei, Taiwan) were adopted to record lung fuction parameters such as FVC and FEV_1. First, subjects were instructed to hold deep breath and let his mouth firmly contact to the mouthpiece. Second, subjects were asked to exhale the air

into the mouth and the process was repeated three times, between each sessions, subjects were allowed to rest at least thirty seconds. Three tests were recorded and the mean value was caculated. The dyspnea situation was evaluated by the questionnaire Baseline Dyspnea Index (BDI) and Transition Dyspnea Index (TDI). The BDI measured the severity of dyspnea at the baseline and the TDI measured the change from baseline. Both questionnaires are composed of three parts: functional impairment, magnitude of task, and magnitude of effort required to evoke dyspnea. Each part in BDI is scored from 0(very severe) to 4(no impairment) and total score from 0~12(the lower the score, the worse the severity of dyspnea) is also recorded. Each component in TDI is rated by seven grades ranging from -3 (major deterioration) to +3 (major improvement). Total score ranged from - 9 to + 9. The lower the score is, the more deterioration of the severity of dyspnea revealed. The minimal clinical important difference(MCID) of TDI is ≥1 unit[31]. The number rating scale NRS is used to define the level of neck pain and stiffness. The MCID of neck pain VAS is 1.5[32]

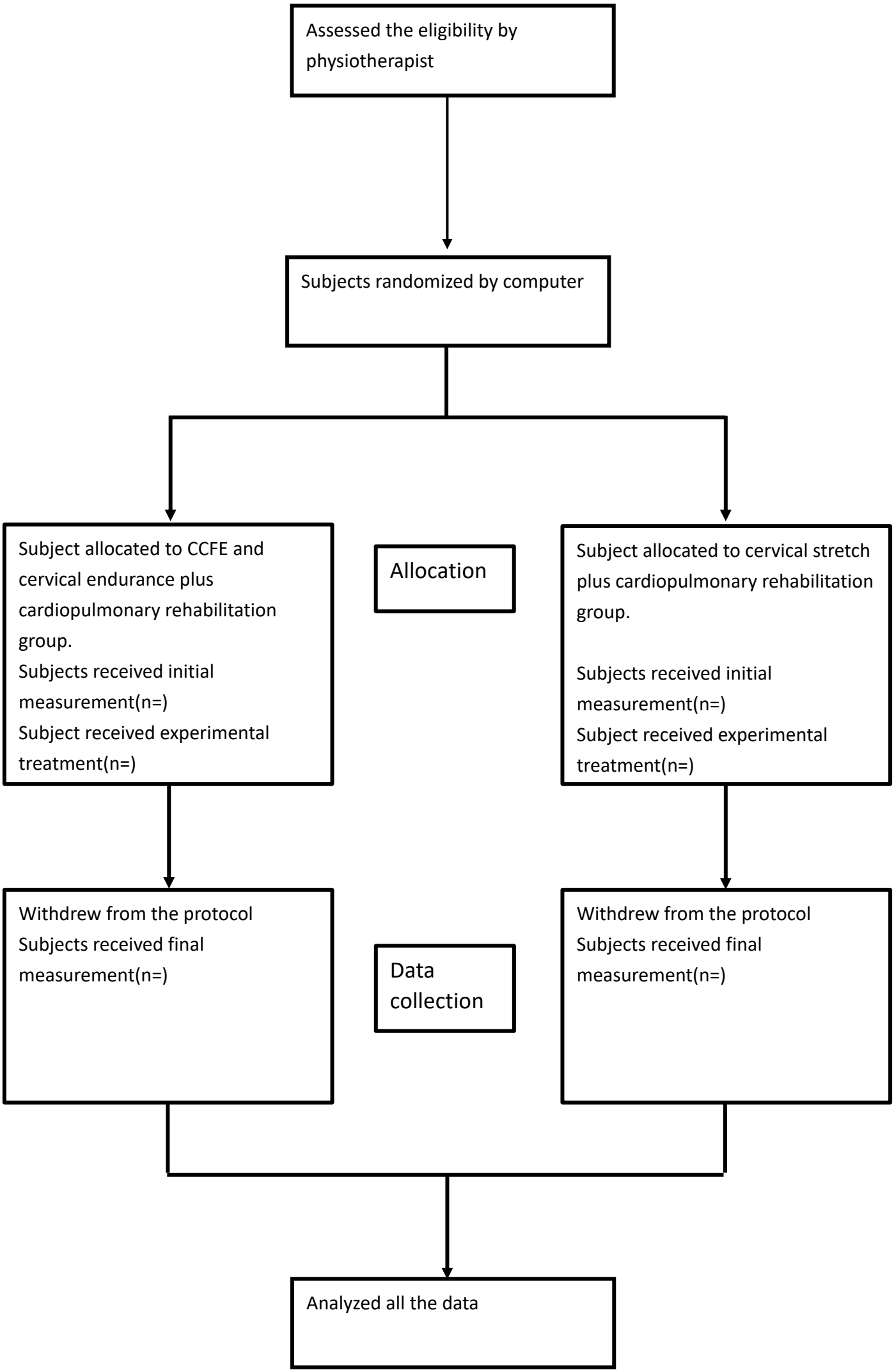
2.4 Treatment

Experimental group is consist of CCFE and neck flexor endurance training plus normal cardiopulmonary rehabilitation. Subjects were instructed to perform chin in without excessive SCM contraction. CCFE was conducted in supine position. Subjects were askd to maintain chin for 10 seconds each repetition, ten repetitions for a set, 3 sets in a treatment session[30]. The physiotherapist with abundant experience related to CCFE supervised all the treatment process to comfirm the quality of execution. If no symptoms revealed, the neck endurance exercise would invole into the treatment sessions. Neck endurance exercise was also conducted in supine position. Subjects were taught to lift their head with a neutral upper cervical spine first. Then, they gradually move the head and neck through as full range as possible without induce discomfort or neck related symptom. This exercise was performed 12~15 reptition depends on patient's condition[33]. If the subjects were unable to achieve the training level, subject's bed were inclined up from horizontal. Hence, the demand of lifting neck and head declined and subjects could perform aimed repetitions. The cardiopulmonary rehabilitation protocol was based on Wu, Y.-T. et al[9], and it was divide into three stages. In first stage, subjects lied in supine position, and they were instructed to do diaphram breath, pursed-lip breath, lateral coastal breath, cough training, and rib mobilization. The dosage and type of therapy were decided depending on subjects situation everyday. The total cardiopulmonary training was controled in 20 minutes. In second stage, the icentive spirometer (picture A) was integrated into the therapy. Subjects were asked to inhale the air slowly with eye contact at the chamber of the spirometer for controling the air flow velocity. Subject were also asked to inhale as many volumes as possible. Back support was inclined to hold subject in semi-sitting position. 15 repetitions was given to subjets and subjects received 20 second rest between each repetition. In addition, some upper extrimities training combined with breath exercise were also involved in after incentive spirometer training. 15 repetitions, 3 sets was given to subjets. In stage 3, the upper extremities exercise were combined with spirometer training. 15 repetitions, 3 sets was given to subjets. The expericed physiotherapist decided the stages depends on patient's capability, that is, the stages were not the same for every subject. The control group were composed of neck stretch exercise plus cardiopulmonary rehabilitation. The neck stretch exercises were executed by physiotherapist before cardiopulmonary training. Neck flexion, neck extension, neck right rotation, neck left rotation, neck right sidebending, and neck left sidebending were applied to subjects 5 times for each direction, and neck maintained at end position for 30 seconds each time.

Statistical Analysis Plan (SAP):

The primary variable of the study were vital capacity, respiratory complication ,and dyspnea. The secondary variable of the study were $FEV_{1,}$ pain and stiffnes of neck. Descriptive statistics for the categorical variable were documented as frequency counts and percentages. The continuous variables were reported as mean + SD, if they were normal distribution, or they were recorded as median and range.

The Wilcox signed test was adopted to analyze the treatment before and after the treatment sessions (time effect). The Mann-Whitney U was applied for the difference before and after treatment between two groups (group effect), and the baseline of two groups was also analyzed by this method. The significant level was set as p value< 0.05. All the statistical data analysis were performed by SPSS version 22.


Assessed the eligibility by physiotherapist
Subjects randomized by computer
Subject allocated to CCFE and cervical endurance plus cardiopulmonary rehabilitation group.
Subjects received initial measurement(n=)
Subject received experimental treatment(n=)
Allocation
Subject allocated to cervical stretch plus cardiopulmonary rehabilitation group.
Subjects received initial measurement(n=)
Subject received experimental treatment(n=)
Withdrew from the protocol
Subjects received final measurement(n=)
Data collection
Withdrew from the protocol
Subjects received final measurement(n=)
Analyzed all the data

Informed Consent Form (ICF):

衛生福利部桃園醫院

醫學倫理及人體試驗委員會受試者同意書

計畫名稱: 頸部穩定運動對於脊髓損傷病人肺部功能之改善

執行單位：復健科　　委託單位 / 藥廠：無

主要主持人：吳昌政　　職稱：主治醫生　　電話：

協同主持人：　　職稱：　　電話：

研究人員：蔡承欣　　職稱：物理治療師　　電話：0936199836

二十四小時緊急聯絡人/電話：蔡承欣 0936199836/分機：1012

1.計畫摘要：脊髓損傷是一種嚴重性的中樞神經傷害，除常見的脊椎受傷部位以下神經支配肌肉動作喪失，感覺異常和喪失外，脊髓損傷病人還會有呼吸系統受損的問題。而本實驗藉由頸部穩定運動和肺部物理治療來改善這些脊髓損傷病人的肺部功能，頸部不舒服，還有呼吸困難問題。

2.研究計畫目的：

探討頸部穩定運動對於脊隨損傷受試者肺功能，頸部不適，和呼吸困難之改善

3.計畫之主要納入與排除條件：

納入條件:

1.發生脊髓損傷一年內的受試者 2. 脊隨損傷的病人的受傷位置在 T12 之上 3.ASIA level ABCD 4.年齡 20~70 歲 5.FEV_1<80%

排除條件:

1.使用呼吸器之受試者 2.有接收氣切之受試者 3.有精神病史且無法遵守指令者 4. 有其他神經疾病者 5. 身體有感染或正在發炎者 6. 有癌症疾病者

4.研究計畫方法及相關檢驗：

研究設計：

本實驗預計收入多名脊髓損傷的受試者，並且以隨機分配的方式將這些受試者分為兩組，一組為頸部穩定運動加一般心肺復健，另一組為一般心肺復健，另外本實驗也會請一位不知實驗分組的評估者來評估兩組間的實驗結果

步驟流程與施測工具:

本實驗流程為收入符合條件受試者後，先進行院內基本肺功能測試，Baseline Dyspnea Index (BDI)（基本呼吸困難指標）量表，疼痛和僵硬 VAS 測試（BDI 以及 VAS 測試會以每星期為切點作一次測試)，測試完之後，會隨機接受兩組不同的治療，一組為頸部穩定運動加一般心肺復健，另一組為一般心肺復健，住院期間（平均 4 星期）內總共接受 10 次治療(若治療未滿 10 次者資料依然會納入分析)，每次至少 30 分鐘，接受所有治療後隔天再進行如同前測知模式進行後測，並且會使用電話訪談方式在受試者出院一個月之後，使用問卷方式追蹤受試者呼吸情況。

統計分析:

本實驗使用 pair-t test 檢定來比較治療前後的各項參數差異，並且使用 independent-t test 來比較兩組前後的差值作為組間治療的差別，統計分析則使用 SPSS 22.0 版，顯著水準為 p value <0.05。

5.可能產生之副作用、發生率及處理方法：

除非受試者未能依照指示運動，才有發生輕微呼吸困難之危險。

6.其他替代療法及說明：

依照病人情況，可能會調降心肺物理治療之強度。

7.計畫預期效益：

1. 增進脊隨損傷病人的肺功能。
2. 改善脊隨損傷病人頸部不適的情形。
3. 改善脊髓損傷病人呼吸困難之情形。
4. 提供新式心肺復健方式給臨床使用者當作參考。

8.研究計畫進行中受試者之禁忌、限制與應配合之事項：

實驗過程中，需全程依照物理治療師指示來來進行運動，請勿自行增減運動劑量，及調整運動模式

9.機密性：

1.本研究採匿名方式進行，凡涉及個人或機構之可辨識資訊將以研究的號碼取代。除了有關機構依法調查外，計畫主持人會確保個別資料的機密與受訪者的隱私。本試驗之受訪對象可能對資料保密有所疑慮，我們將詳細說明本試驗資料保密的步驟及可行性，若受試者仍有疑慮，可隨時退出本試驗。

2. 本實驗完成後，該資料即刪除不做其他用途。

10.損害補償與保險：

1.如依本研究所訂臨床試驗計畫，因發生不良反應造成損害，由桃園醫院及計畫主持人共同負補償責任。但本受試者同意書上所記載之可預期不良反應，不予補償。

2.如依本研究所訂臨床試驗計畫，因而發生不良反應或損害，本醫院願意提供專業醫療照顧及醫療諮詢。您不必負擔治療不良反應或損害之必要醫療費用。

3.除前二項補償及醫療照顧外，本研究不提供其他形式之補償。若您不願意接受這樣的風險，請勿參加試驗。您不會因為簽署本同意書，而喪失在法律上的任何權利。

A、試驗過程中，與你（妳）的健康或是疾病有關，可能影響你（妳）繼續接受臨床試驗意願的任何重大發現，都將即時提供給你（妳）。

B、如果你（妳）在試驗過程中對試驗工作性質產生疑問，對身為患者之權利有意見或懷疑因參與研究而受害時，可與本院之醫學倫理及人體試驗委員會聯絡請求諮詢，其電話號碼為：03-3699721 分機 8341

C、為進行試驗工作，**你（妳）必須接受吳昌政醫師的照顧**。如果你（妳）現在或於試驗期間有任何問題或狀況，請不必客氣：**可與在桃園醫院復健科的蔡承欣治療師聯絡（24 小時聯繫電話：0936199836）**。本同意書一式 2 份，已將同意書副本交給你（妳），並已完整說明本研究之性質與目的。

12.試驗之退出與中止：
您可自由決定是否參加本試驗；試驗過程中也可隨時撤銷同意，退出試驗，不需任何理由，且不會引起任何不愉快或影響其日後醫師對您的醫療照顧，試驗主持人或贊助廠商亦可能於必要時中止該試驗之進行。

13.受試者資訊：
受試者姓名：　　性別：　　出生日期：　/　/

法定代理人/有同意權人姓名：

14.簽名
A、主要主持人、或協同主持人已詳細解釋有關本研究計畫中上述研究方法的性質與目的，及可能產生的危險與利益。

主持人/協同主持人簽名：
日期：　年　月　日

解說人員簽名:
日期：　年　月　日

B、受試者已詳細瞭解上述研究方法及其所可能產生的危險與利益有關本試驗計畫的疑問，業經計畫主持人詳細予以解釋。本人同意接受為臨床試驗計畫的自願受試者。

受試者簽名：　　日期：　年　月　日

法定代理人簽名：
日期：　年　月　日

有同意權人簽名：
日期：　年　月　日

C、見證人：姓名：
身分證字號：　　聯絡電話：
通訊地址：
簽名：　　日期：　年　月　日

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